of sixteen countries from the region according to different criteria: characteristics, quality (using Drummond's checklist), use of local data, addressed inputs limitation and results transferability. **RESULTS:** Economic evaluations are used in CEE countries for informing decision making, while critically considering methodology, quality and study's reliability. Experts acknowledged limited generalizability of study results both between and within geographic regions. Meanwhile, despite these constraints, facing limited health technology assessment (HTA) capacity experts were still using foreign evidence. At the same time, the usefulness of studies published in CEE and former Soviet countries to inform their decision making is limited because of insufficient transparency in reporting, unaddressed uncertainty, limited insight on inputs and transferability of results. Although local costs, baseline risk and resource use data are required, experts accept evidence originating from health care settings outside CEE and former Soviet countries regarding relative effect and utilities values. **CONCLUSIONS:** HTA priority setting and transferability assessment of economic evidence are important issue in health care decision making in CEE and former Soviet countries, since HTA research capacity is limited and local evidence is scarce. For this purpose, quality, transparency, and transferability should be addressed explicitly in published economic evaluations originating from CEE and former Soviet countries.

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TEN YEARS OF DEVELOPMENT STUDIES IN HEALTH TECHNOLOGY ASSESSMENT IN BRAZIL: PROFILE OF STUDIES AND OPERATIONAL INDICATORS

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BACKGROUND: The Department of Science and Technology (DECIT) at the Ministry of Health (MoH), since 2003, has financed studies to support demands from the MoH technical areas regarding the decision making process about health technologies. **OBJECTIVES:** To analyze DECIT performance in financed Health Technology Assessment (HTA) studies to improve the capacity building of HTA in Brazil. **METHODS:** A retrospective descriptive study based on the analysis of documents and official records built in a single database in Excel containing the studies promoted by DECIT from 2003 to November 27, 2013. The variables pre-classified and collected from Brazilian Network for Health Technology Assessment's database, SISREBRATS, were revised by two reviewers and conferred or supplemented with data from the Database of Health Research, Annual Reports Management by DECIT, and Final Reports and Cooperation Agreements by co-financier partners. **RESULTS:** 284 HTA projects were financed entirety for R$ 25 million (± R$ 1,69 million) between 2003 and 2013. The average value financed was R$ 346 thousand and the average bias was ± RS 61 thousand. Of these, 57% (162/284) are pharmacotherapy; and 35% (99/248) are systematic reviews. The majority of the studies 58% (165/284) were financed by MoH calls in years 2005 to 2010 and contributed to 110 masters and doctors conclusions in HTA landfield. **CONCLUSIONS:** These numbers show despite the HTA culture in Brazil having been in its initial stage, DECIT is increasing its capacity to respond to demands with a variety of studies types, specily in pharmacotherapy. However, evaluation demands do not always correspond to health needs of promotion and prevention.

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THE DEFINITION AND ROLE OF QUALITY OF LIFE IN GERMANY'S EARLY ASSESSMENT OF DRUG BENEFIT

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OBJECTIVES: Since January 2011, pharmaceutical manufacturers are obliged to submit dossiers presenting benefits over comparative treatment when launching new products in the German pharmaceutical market. These dossiers are usually evaluated by the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the dossier, the IQWiG's evaluation and a subsequent hearing process, the Federal Joint Committee (G-BA) decides on additional therapeutic benefit related to mortality, morbidity, quality of life (QoL) and side effects. As QoL is among the more contested of these criteria and remains comparably unspecified, this qualitative study's aim was to analyze definitions and the role of QoL in early assessments of benefit (EAB) in Germany. **METHODS:** As most of the documents are freely available on the G-BA's website, this study included all relevant documents of the first completed 66 assessments (11.2011-12.2013). We conducted a qualitative content analysis screening the dossiers, IQWiG evaluations, G-BA decisions and the protocols of the oral hearing for relevant links to QoL and synonyms. In a process of independent analysis and joint consensus building by two researchers, relevant text passages were extracted and reduced to key content on the term's usage. During analysis, a system of codes was developed accounting for a wide variety of recurring QoL-related definitions and references to its importance. **RESULTS:** Even though key players did not necessarily share the same QoL-definition, the concept's relative importance was highlighted in numerous references. G-BA decisions criticize the lack of or the inadequate presentation of QoL data in the manufacturer's dossiers. G-BA and IQWiG apply a narrow understanding of QoL, while manufacturers failed to establish wider notions of QoL linking factors such as patient satisfaction to the concept. **CONCLUSIONS:** QoL in a particular sense is of pivotal importance in Germany's early assessment of benefit. The demand for reliable QoL data is growing.

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AN UPDATE ON CLINICAL AND ECONOMIC EVIDENCE REQUIREMENTS FOR ADVANCED-THERAPY MEDICINAL PRODUCTS IN EUROPE

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OBJECTIVES: Advanced-therapy medicinal products (ATMPs), such as gene therapy, cell therapy and tissue engineering are a new class of medicines in the EU. ATMPs offer prospects in prevention and treatment of fatal and/or chronic debilitating diseases where no effective treatments exist. However, with complicated mechanisms of actions and benefits often being anticipated in the longer term, it is challenging to demonstrate hard clinical evidence and create robust cost-effectiveness models that Payers have come to expect at the launch of pharmaceuticals. Thus, manufacturers face difficulties when negotiating the price for ATMPs and may not be able to realize their full potential. This paper aims to use case studies of ATMPs launched in EU5 to outline access pathways and review the clinical and economic evidence requirements. **METHODS:** Secondary research identified ATMP approvals since 2008 and a framework was created to develop hypotheses on clinical and economic evidence requirements, considering alternative routes to market. Hypotheses were then validated during in-depth interviews with key stakeholders across EU5. **RESULTS:** Payers are yet to be convinced about the full benefit of ATMPs and are reluctant to pay premium prices if they are not sure about long-term efficacy and safety. Additionally, in their cost-benefit analyses, Payers tend to consider only the direct costs associated with a condition, ignoring broader societal benefits and savings in the long run. Therefore, price negotiations are sometimes lengthy. Risk sharing and novel payment-by-result schemes are often agreed to mitigate risks. **CONCLUSIONS:** Payers are not yet familiar with the potential value of ATMPs, and, in most cases specific evaluation criteria don't exist. Manufacturers need to invest in educating Payers on the huge differences between ATMPs and traditional therapies, particularly to show that manufacturing costs are substantial, and work together to identify relevant measures for clinical and economic evaluations of this new therapy class.

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ROMANIAN QUICK-HTA DEVELOPMENT IN 2013

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OBJECTIVES: The Objectives are to present the characteristics of the quick-HTA started in June 2013 and to show the Results of the first quick-HTA process in Romania. **METHODS:** The health care context and the Romanian legislation covering HTA were studied by considering: the reasons behind HTA introduction, the key stakeholders and the HTA process. A critical appraisal was done covering public HTA reports and the decisions taken by the Ministry of Health (MofH). **RESULTS:** The introduction of quick-HTA began mid-June 2013 when MofH released the legislation and the HTA Unit started receiving dossiers for new drugs/indications. The HTA model was based on a "score-card" system with 6 criteria: HAS (France) opinion, NICE/SMC/AWMSG (UK) opinion, the number of EU countries with reimbursement, relative efficacy, relative safety and relative patient-reported-outcomes (PRO), but no role of budget impact. From June to December 2013, 167 HTA dossiers were evaluated by the HTA Unit with an acceptance rate of about 80%. Most of the drugs accepted for reimbursement were oncological (23%); other main therapeutic areas were diabetes with 16 drugs/indications receiving positive evaluations, rheumatology (14), oncohaematology (8) and neurology (7). The HTA included also biosimilars, all 4 of them receiving positive decisions. Unfortunately, early 2014, the new Government abrogated this HTA legislation and the already-published HTA reports, claiming that the process didn't mentioned the criteria for de-listing reimbursed drugs nor the budget impact, within HTA reports. Moreover, the HTA process was moved into the responsibility of the National Agency for Drugs. **CONCLUSIONS:** The implementation of the quick-HTA in Romania took a good start, using a mixture of information, from benefits and cost-effectiveness in other countries, to relative effectiveness, safety and PRO. However, the lack of consideration for the local context and the political disagreements led to a temporary suspension of this quick-HTA process in Romania.

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HTA IN THE BRAZILIAN HEALTH CARE SYSTEM AND POTENTIAL LESSONS LEARNED FOR OTHER BRICS STATES

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OBJECTIVES: The objective of the study was to provide an external assessment of recent HTA institutionalization in Brazil, and identify a set of lessons learned potentially applicable to BRICS States. **METHODS:** This research is based on a quantitative and qualitative assessment. A literature survey between 2000 and 2014 was conducted in English, Spanish and Portuguese in PubMed/Medline, Science Direct, LILACS and SciELO. Epidemiological and socio-economic data was retrieved from national health accounts as well as WHO/PAHO, OECD and World Bank. For the Brazilian National Committee for Incorporation of Technologies (CONITEC), available reports on the incorporation of medicines into the National Unified System (SUS) for the first two years of operation (2012 and 2013) were analyzed. A matrix containing quantitative and qualitative criteria was elaborated to analyze reports by the outcome of decision, therapeutic class, author (s) of the request and public consultation. **RESULTS:** A total of 92 available CONITEC reports for 2012 (n=38, 33 for medicines) and 2013 (n=54, 42 for medicines) were analyzed. 45% of reports on medicines recommended incorporation into the SUS. Most of the positive recommendations were clearly related to public health priorities as identified by the government, translating a strong commitment for improved access to medicines within the SUS i.e. anti-cancer drugs. Overall, the creation of the CONITEC represents a substantial step toward the institutionalization of HTA, with more transparency and accountability in decision-making processes, considering ethical, organizational, social, and legal aspects. **CONCLUSIONS:** Whereas lowest in Russia, India and South Africa, and at a transitional stage in China, Brazil has a comparable degree of institutionalization of HTA as countries with a long-lasting HTA experience. A best-practice assessment in the area of HTA within the BRICS has still to be elaborated. Transferability of lessons learned might be a strong tool for improving HTA development within the BRICS.

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IS G-BA STRATEGICALLY DISCOUNTING THE BENEFIT ASSESSMENT OF RELATIVELY HIGH COST DRUGS?

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